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COLEMAN SUDOL SAPONE
714 COLORADO AVENUE
BRIDGEPORT, CT 06605

EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,243

Applicant(s)

SKLAR ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 51-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/03, 12/01.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I (claims 1-50) in the reply filed on October 12, 2004 is acknowledged. The traversal is on the ground(s) that since the claims are related, an examination of all the claims can be done with administrative efficiency, and without being unduly burdensome. This is not found persuasive because the different groups require different searches and considerations and thus would place a serious burden on Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 51-78 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10, line 2, recites the limitation "said fluid flow stream". It is not clear as to whether this fluid flow stream is the first or second fluid flow stream.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 16-18, 21, 24, 29-34, 42-44, 46, 47, 49 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferrari, 2,933,293.

A to claims 1 and 34, Ferrari discloses an apparatus (10), (col. 2, line 2) comprising:

first driving means (pump 12 for introducing sample, col. 2, line 7, and see “sample” in figure 1) for driving a plurality of reagent samples from a plurality of source wells (28), (col. 4, line 41) into a first fluid flow stream (col. 2, lines 13-14, and lines 58-61);

second driving means (pump 12 for introducing air, col. 2, lines 57-59; and see figure 1) for introducing a separation gas between each of said plurality of reagent samples in said first fluid flow stream;

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means for driving a second fluid flow stream (pump 12 for introducing reagent, col. 2, line 7, and see "reagent" in figure 1) comprising a plurality of particles (i.e., the reagent);

a junction device comprising:

a first inlet port (i.e., port near "sample" in figure 1) for receiving said first fluid flow stream;

a second inlet port (i.e., port near "reagent" in figure 1) for receiving said second fluid flow stream;

a first reaction zone (at 30, or alternatively, near 44; see col. 2, lines 41 and 42) for forcing mixing between said first fluid flow stream and said second fluid flow stream to thereby form a reaction product stream; and

an outlet port (distal end of 30, or alternatively distal end of 44) for allowing said reaction product stream to exit said junction device;

a second reaction zone (all of 44 or alternatively, distal end of 44) where said plurality of reagent samples and said plurality of particles mix to form a plurality of reaction products, said reaction zone communicating with said outlet port;

reaction product driving means (pump, figure 1, lines 7-10, and line 25, and lines 61-62) for driving said reaction product stream through said reaction zone; and

means (46) for selectively analyzing said reaction product stream for said reaction products.

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As to claim 16, the apparatus further comprises a first tubing (i.e., tubing near "sample" in figure 1) for containing said first fluid flow stream, a second tubing (i.e., tubing near "reagent" in figure 1) for containing said second fluid flow stream and a reaction product tubing (30, or alternatively, tubing near 44, see fig. 1, and col. 2, lines 41-42) for containing said reaction product stream.

As to claim 17, the apparatus includes a unibody flow apparatus (see fig. 1) comprising said first tubing, said second tubing, said reaction product tubing, and said junction device.

As to claims 18, 21 and 24, said first tubing, second tubing, and reaction product tubing comprise high speed multi-sample tubing (col. 2, lines 57-59, disclosing multi-samples in the tubings, the multi-sampling being considered high speed, a relevant term).

As to claim 29, said separation gas comprises air (col. 2, line 57.)

As to claims 30-33, the apparatus is capable of sampling a plurality of homogenous or heterogeneous samples, and capable of introducing particles comprising biomaterials fluorescently tagged (col. 1, lines 15-20). (Examiner notes that Applicant is claiming a device, and that the limitations in claims 30-33 are directed to intended use, and that the prior art device is capable of performing the intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of

performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963.))

As to claim 42, the apparatus further comprises a means (i.e., tubing for primary or secondary processing medium, and pump in figure 1) for injecting a buffer fluid between adjacent reagent samples in said first fluid flow stream. (Examiner notes that the limitation regarding injection of a buffer fluid relates to an intended use, and that the prior art is capable of injecting a buffer fluid through the primary or secondary medium inlets in figure 1.)

As to claim 43, the device is capable of providing a drug as one of said plurality of reagent samples. (Examiner notes that this limitation relates to an intended use, and that the prior art is capable of performing this intended use.)

As to claim 44, said junction device is Y-shaped (see figure 1, above the reference number 44, showing a Y-shape.)

As to claim 46, said junction device is T-shaped (see figure 1, above the reference number 44, showing a sideways "T".)

As to claim 47, a first inlet tube (see near "sample" in fig. 1) and first inlet port (see near "sample" in fig. 1) have the same diameter, a second inlet tube (see near "reagent" in fig. 1) and second inlet port (see near "reagent" in fig. 1) have the same diameter, and an outlet tube (see near distal end of 30, or alternatively distal end of 44) and outlet port (see distal end of 30 or distal end of 44) have the same inner diameter (see fig. 1.)

As to claim 49, said first inlet port and said second inlet port have the same inner diameter and said outlet port has a different inner diameter from said first inlet port and second inlet port (see fig. 1.)

As to claim 50, said outlet port has a larger inner diameter than said first inlet port and said second inlet port (see fig. 1.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari, 2,933,293.

Ferrari discloses the invention substantially as claimed (see above), except for the first, second and outlet ports having the diameter as claimed.

However, it would have been obvious to form the tubings, including inlets, having an inner diameter or wall thickness as claimed since such diameters and thickness provide an optimum or workable range of diameters, and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

3. Claims 19, 20, 22, 23, 25-26 and 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari, 2,933,293, in view of Kercso et al., 6,132,685.

Ferrari discloses the invention substantially as claimed (see above).

As to claims 35-39, although Ferrari teaches sample vessels (28), (col. 4, line 41), Ferrari does not specifically teach that the number of source wells is 72, 96, 384 or 1536.

Kercso, like Ferrari, discloses a device for analyzing a large number of sample compounds. The samples are contained in standard microtiter plates such as those having 96, 384, 1536 number of wells (col. 3, lines 1-3), and are transferred by autosampling sequentially from the wells into a channel (col. 11, lines 45-50, and col. 15, lines 49-54.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide 96, 384, and 1536 as the number of source vessels, as taught by Kercso, or alternatively, 72 source vessels, in the Ferrari device as well known and conventional numbers of source vessels for autosampling as taught by Kercso, as would be desirable for rapid analysis of a large number of samples.

As to claims 19, 20, 22, 23, 25-26, Ferrari does not disclose that the first tubing comprises PVC and has the specific inner diameter as claimed, or wall thickness as claimed.

Kercso teaches that the channels in the device are formed from PVC (col. 10, line 45-46, line 54, and col. 11, line 2.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the Ferrari channels from PVC, as taught by Kercso, as well known and conventional materials used for forming channels for diagnostic bioassays.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the tubings, including inlets, having an inner diameter or wall thickness as claimed since such diameters and thickness provide an optimum or workable range of diameters, and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

4. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari, 2,933,293, in view of Yon-Hin et al., 6,440,645.

Ferrari discloses the invention substantially as claimed (see above), except for the angle between any two of said first inlet port and second inlet port and said outlet port being 120 degrees.

Yon-Hin, similar to Ferrari, discloses an assay device for introducing a sample and reagents, the device having a first inlet port, second inlet port and an outlet port (col. 4, lines 45-49, and col. 5, lines 34-37, and figure 4.) Yon-Hin further discloses an

embodiment wherein any two of said first inlet port and second inlet port and said outlet port being 120 degrees (see figure 4.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the Ferrari first and second inlet port, and the outlet in the configuration as taught by Yon-Hin, as a well known and conventional configuration for providing inlet ports and outlet ports for introduction and mixing of samples and reagents.

5. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari, 2,933,293, in view of Knapp et al., 6,235,685.

Ferrari discloses the invention substantially as claimed (see above), except for said first inlet port, second inlet port and outlet port each having the same interior diameter.

Knapp, similar to Ferrari, disclose a diagnostic assay device having separate channels (1350 and 1355) for samples and reagents, and an outlet port (near mixing zone, 1345), (see figure 13.) Knapp discloses an outlet port and outlet tube having the same interior diameter as the inlet ports for the samples and reagents (see figure 13.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide in the Ferrari device inlet ports for samples and reagents having the same diameter as the outlet port and outlet tube, as taught by Knapp, as a

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well known and conventional configuration for providing inlet ports and outlet ports for introduction and mixing of samples and reagents.

6. Claims 2-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari, 2,933,293, in view of Saros et al., 4,853,336.

Ferrari discloses the invention substantially as claimed (see above). More specifically, Ferrari teaches an assay device (col. 1, lines 18-20, and col. 2, lines 31-32 and 45) and an inlet for providing fluid samples, air, and reagents (col. 2, lines 9-3, and lines 29-30.) However, Ferrari does not disclose the particular means for introducing fluid samples, air and reagents.

More specifically, as to claims 2-7, Ferrari does not disclose an autosampler as claimed for introducing fluid samples, air and reagents.

Saros, like Ferrari, discloses an assay device having means (col. 6, lines 31-32) for mixing fluid samples and a reagent, and detector means (112) for analyzing the mixture. Saros further discloses an autosampler (20, 30 and 60; col. 4, line 37, lines 54, and col. 5, line 1) for introducing fluid samples, air and reagents into the assay device. The autosampler provides an automated means with a controller (10) for aspirating multiple aliquots of fluid samples from fluid sample sources (col.4, lines 50-51) and reagents from reagent sources (col. 4, lines 59-60), and for aspirating air (col. 5, lines 1-2).

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As to claim 3, said autosampler includes a probe (62) and said mixing apparatus includes a means (controller 10, col. 5, lines 1-5) for exposing a probe tip of said probe to a jet of gas to remove liquid from said probe tip (i.e., aspiration).

As to claim 4, said autosampler includes a probe having a conical tip (62, in fig. 1).

As to claims 5-7, said autosampler includes a hydrophobic probe (i.e., probe is formed from hydrophobic material, col. 5, line 43).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the autosampler as taught by Saros in the Ferrari assay device as the means for introducing fluid samples, air and reagents, as would be desirable for an automated introduction of materials for efficiently carrying out diagnostic assays.

As to claims 8-15, Ferrari discloses that the pump (12) may be of any suitable type pump for pumping samples, processing liquids and air (col. 2, lines 7-10). Moreover, as to claim 10, Ferrari discloses a pump located along said first fluid flow stream between sample/air/reagent inlets and the junction device (see fig. 1.)

However, Ferrari does not give a specific example of a type of pump. More specifically, Ferrari does not teach that the first driving means comprises a first fluid flow steam peristaltic pump (claim 8). (For claim 9, see above rejection regarding multiple-sample tube disclosed by Ferrari.)

Saros however discloses an assay device having means for introducing fluid samples, air and reagents (col. 5, lines 1-2, and col. 6, lines 31-32.) Saros further

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discloses that the means for pulling all fluids into and through the system is a peristaltic pump (120), (col. 6, lines 52-54.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a peristaltic pump as the specific pump in the Ferrari device as the means for pulling all fluids into and through the system as taught by Saros, as a well known and conventional pump used to move fluids in an assay device. Given the teachings of Ferrari and Saros, one of ordinary skill in the art would have a reasonable expectation of success.

As to claim 11, said second driving means comprises a second fluid flow stream peristaltic pump (i.e., the same peristaltic pump.)

As to claim 12, see rejection above regarding multi-sample tube.

As to claims 13-15, it would have been obvious to provide the same peristaltic pump as the first fluid flow stream peristaltic pump, second fluid flow stream peristaltic pump, said reaction product driving means, since both Ferrari and Saros disclose a single pump for moving all fluids and air (see figure 1 in Ferrari, and col. 6, lines 53-54 in Saros.)

7. Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari, 2,933,293, in view of Manns, 5,679,310.

Ferrari discloses the invention substantially as claimed (see above). Although Ferrari teaches sample vessels (28), (col. 4, line 41), Ferrari does not specifically teach

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wells having conical shape (claim 40), nor well plate mounted in an inverted position (claim 41.)

Manns, like Ferrari, teaches multiwell test plate (20). Manns further teaches that the microtiter plates may be inverted, and conical in shape (col. 6, lines 57-58.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the Ferrari sample vessels into an inverted and/or conical shape, as a well known and conventional shape for microtiter wells as taught by Manns.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822.

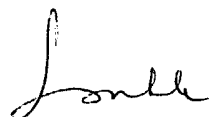
The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

1/7/05